

ADDITIONAL FEES

One (1) additional independent claim and six (6) additional claims in excess of 20 are being filed herein and the Small Entity Fees therefor are \$184.00. A check in the amount of \$184.00 is being enclosed herewith to pay the additional claim fees for Claims 32 through 37 being filed herein.

In addition, a check in the amount of \$55.00 paying the Small Entity Statutory Disclaimer Fee of \$55.00 required under 37 CFR 1.20(d) for filing a Terminal Disclaimer is also being paid herewith.

No additional fees are deemed due herein. However, if any additional fees are required for any reason, please charge the same to Deposit Account No. 13-2515.

REMARKS**Claims**

Claims 1 through 31 are pending in the Application and new Claims 32 through 35 are being added by amendment.

Claims 20 through 28 have been allowed.

Claims 1-19 and 29-32 have been rejected.

Claims 19 and 30 would be allowable if re-written to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office Action and to include all of the limitations of the base claim and any intervening claims.

Drawing

The Examiner objected to the drawings as failing to comply with 37 CFR 1.84(p) (5).

The objections set forth on page 2, in Paragraphs 1 and 2 of the Office Action have been overcome as follows. In the Specification at Page 45, line 18, the reference to "area 272" has been deleted, it being noted that Fig. 27 illustrates a

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section in lieu of an area, and replacing the same with --section 248-- . Reference numeral 248 is shown on the drawing and the use of the word "section" is supported by the drawing and Specification.

In the Specification at Page 45, line 19, the numeral "252" has been deleted and replaced with numeral --232-- which is shown in Fig. 27 of the drawing.

The Specification at Page 46, Line 6 references the numeral "276" which is not shown in Fig. 28 of the drawing.

Accordingly, Sheet 7 of the Drawing, at Fig. 28 has been amended by adding a lead line and numeral "276" as shown in "red" on the enclosed Sheet of Drawing.

The Examiner is respectfully requested to approve this drawing correction.

In summary, the reference to element 252 has been deleted and element 276 has been added to the drawing. Elements 232 and 248, as shown in the drawing, are now properly referenced in the Specification at Page 45, lines 18 and 19 as discussed above.

For all of the above reasons, the Examiner's objection to the drawings has been overcome.

Specification

The Examiner has objected to certain informalities in the Specification.

Applicant has carefully reviewed the entire Specification and agrees with the Examiner's objection as the terms "thin elongated lip" and "thin elongated lip" have been used interchangeably. The review further disclosed that the term "an external retaining member" was used in the Abstract and in the Specification at Page 10, line 9 and 10. Variations of these terms were used elsewhere in the specification.

Accordingly, since Applicant has defined the term "thin elongated lip" in the Specification at page 23, lines 13 through 22, that term should be used throughout the Specification for consistency. As such, the Specification has been amended as necessary to use the term "thin elongated lip" in lieu of the term "thin retaining lip".

The Specification clearly recites that the "thin elongated lip" has a "posterior surface" at Page 23, line 17. The words "central edge" was not defined in the Specification. As such, the Claims 2 and 3 have been amended as follows such that the Specification provides an antecedent basis for the claim language.

Claim 2 has been amended at lines 3 and 6 by deleting "edge" and replacing the same with --surface-- such that the reference is now to a "posterior surface".

Claim 3 has been amended at lines 4 and 7 to delete the word "edge" and to replace the same with the word --surface-- such that the reference is now to a "posterior surface". Further, Claim 3 has been amended at line 4 by deleting the word "edge" and amending the claim language to read

"having a portion of the posterior surface
removed adjacent the central axis and wherein
said central axis is co-axial and aligned
with the elongated axis of said elongated
member to position the * * *"

With respect to Claim 18, the word "starter" at line 3 has been deleted and replaced with the word --starting-- such that the term is now "starting tip". An antecedent basis exists at numerous locations with in the Specification, the term "starting tip" at Page 22. Line 21 being exemplary.

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For the above reasons, the Examiner's objection to the specification has been overcome.

In reviewing the Specification, several other minor changes were made to correct the language or grammar of the Specification.

The Examiner's attention is directed to the changes made to the Specification at Page 23 at lines 17 through 19 wherein the wording of the sentence was amended to clearly recite that the posterior surface is "free from protruding into, or from contacting with or abrading the surface of an eye including the cornea or conjunctiva". A similar amendment was made at Page 25, line 13. This is clearly disclosed by the Specification and drawing. The use of the word "conjunctival" was changed to -- conjunctiva-- at saved locations in the Specification.

All of the amendments to the Specification made herein are disclosed by or have an antecedent basis in the Specification, Drawings or Claims, and no new matter has been added by such amendments.

Claim Objections

The Examiner objected to Claim 2 under 37 CFR 1.75(c) as being in improper dependent form.

Claim 2 has been amended at line 2 to now be dependent on Claim 1, and as such is now in proper dependent form and further limits the subject matter of previous Claim 1.

For these reasons, the objection to claim 2 has been overcome.

Claim Rejections - 35 USC § 112

The Examiner has rejected Claims 2-4 and 18 under 35 U.S.C. 112, first paragraph.

Claims 2 and 3 have been amended to use language therein having an antecedent basis in the Specification.

Claim 2 has been amended at lines 3 and 6 by deleting "edge" and replacing the same with --surface-- such that the reference is now to a "posterior surface".

Claim 3 has been amended at lines 4 and 7 to delete the word "edge" and to replace the same with the word --surface-- such that the reference is now to a "posterior surface". Further, Claim 3 has been amended at line 4 by deleting the word "edge" and amending the claim language to read

"having a portion of the posterior surface removed adjacent the central axis and wherein said central axis is co-axial and aligned with the elongated axis of said elongated member to position the * * *"

Claim 4, which is dependent on Claim 2 and based on independent Claim 1, has not been amended in that the language used therein, such as for example "thin elongated lip" at line 3, has an antecedent basis in Claim 1.

With respect to Claim 18, the word "starter" at line 3 has been deleted and replaced with the word --starting-- such that the term is now "starting tip". An antecedent basis exists at numerous locations with the Specification, the term "starting tip" at Page 21. Line 21 being exemplary.

For all of the above reasons, the Examiner's rejection of Claims 2-4 and 18 under 35 U.S.C. 112, first paragraph, has been overcome.



The Examiner has rejected Claims 1-4, 8, 12-19, and 29-32 under 35 U.S.C. 112, second paragraph.

With respect to Claim 1, the word "tip" at line 5 has been deleted and replaced with --lip-- such that the reference is now to "the thin elongated lip--.

With respect to Claim 2, Claim 2 has been amended at line 1 to now be dependent on independent Claim 1.

Further, Claim 2 has been amended at line 4 to delete the word "control" and to replace the same with the word --central-- such that the reference is now to "said central axis". An antecedent basis therefor exists at line 3.

With respect to Claim 3, Claim 3 has been amended at line 3 by deleting the word "its" and amending the language to read:

"having a portion of the posterior surface
removed adjacent the central axis* * * "

With respect to Claims 8, 12 and 17, the word "same" has been deleted and replaced with the appropriate element. In Claim 8, the word "same" at line 5 has been deleted and replaced with --collapsible flared section--. In Claim 12, the word "same" at line 10 has been deleted and replaced with --collapsible flared section--. In Claim 17, the word "same" at line 4 has been deleted and replaced with --collapsible flared section--.

With respect to Claim 18, the word "tip" at line 7 has been deleted and replaced with the word --lip-, such that the term now reads "thin elongated lip", an antecedent basis for which is present at line 4.

With respect to Claim 19 which is dependent on Claim 18, as amended, the term "the starting tip" as used at line 3 is correct and an antecedent basis exists therefor in Claim 18, as amended, at line 4.

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With respect to Claim 29 at line 9, the article "said" has been deleted and the word "includes" has been deleted and replaced with --including-- such that the phrase now reads "a starting tip including". Further, at line 16, the word "tip" has been deleted and replaced with --lip--, such that the phrase now reads "thin elongated lip", an antecedent basis for which is present at line 14.

With respect to Claim 30, Claim 30 has been amended at line 4 by inserting the words "thin elongated" before the word "lip" such that the term now reads "thin elongated lip", an antecedent basis for which exists in Claim 29 at line 14. In this manner, the rejections under 35 USC 112, first and second paragraphs, applicable to Claim 30 have been overcome.

With respect to Claim 31, at line 12, the words "thin retaining lip" have been deleted leaving the phrase as "thin elongated lip". Further, at line 14, the word "tip" has been deleted and replaced with the word --lip--, making the phrase "the thin elongated lip", an antecedent basis for which exists at line 12.

With the above amendments and reason set forth above, the Examiner's rejections of Claims 1-4, 8, 12-19, and 29-32 under 35 U.S.C. 112, second paragraph, have been overcome.

Claim Rejections - 35 USC §102

The Examiner rejected claims 1 through 4 under 35 U.S.C. § 102(b) as being anticipated by Guena et al. United States Patent 5,417,651.

In making this rejection, the Examiner stated as follows:

With respect to claims 1-4, see Figures 1 and 4 for a punctum plug (10) comprising an elongated member (2) having a thin elongated

lip (3) which is positioned in a generally anterior direction upon insertion in to a punctum opening, the thin elongated lip having a posterior edge which is positioned away from the cornea, the central axis being coaxial with the elongated axis of the elongated member, wherein one end is curved anteriorly relative to the thin elongated tip.

Applicant respectfully traverses this rejection for several important reasons.

Guena et al. relates to a punctum plug and a monocanalicular probe for lacrimal pathology, namely, to treat a condition where one of two canaliculi are stenosed which causes the tears to drain off a patient's cheek in lieu of flowing through the tear ducts and out the nose. Guena et al. discloses a monocanalicular probe for a lacrimal pathology comprising a duct plug having a symmetry axis including a flange, a neck and a bulb, wherein a tip extends laterally from the bulb in a direction about perpendicular to the symmetry axis of the plug. A flexible tube is adhered to the tip of the plug and the tube is ended by a mandrel.

The present invention covered by Claims 1 through 4 does not relate to a lacrimal pathology device, but relates to a implant which occludes the lacrimal canaliculus for treatment of eye disease.

Further, Guena et al. discloses and teaches at column 2, lines 60 through 65, to wit:

The flange 3 is tilted relative to the axis of symmetry X of the plug. The tilting of

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the flange allows [the flange] to have full contact between the cornea and the flange thereby avoiding irritation [Underlining added for emphasis].

Guená et al. states at column 1, lines 36 through 38, the following about the prior art Freeman Plug disclosed in United States Patent 3,949,750:

The head is dome shaped to allow it to rest in the lacrimal pool and against the conjunctiva and cornea with little irritation [Underlining added for emphasis].

The present specification at Page 13, lines 9 through 16 discloses that one disadvantage of the prior art devices is that the edge of the caps contacts and abrades the cornea and the Specification states:

The other known punctum plugs have a convex dome or collarette to act as a cap to prevent the punctum plug from migrating through the punctum opening, through the vertical portion of the canaliculus, into the ampula or sac or into the medial position of the horizontal portion of the canaliculus. Such caps are generally circular in shape and result in an edge which engages, contacts or otherwise abrades the cornea [Underlining added for emphasis].

Clearly, one of the disadvantages of the prior devices including Freeman and Guená et al. is that an edge of the circular cap, dome or flange engages, contacts or otherwise

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abrades the surface of the eye including the cornea and conjunctiva.

It is highly desirable and important to not have the surface of the eye including that conjunctiva and cornea be contacted by and/or abraded by the implant. Such a condition typically causes trauma to the eye and is detrimental to the treatment of disease in the eye. In certain instances, the abrasion of the conjunctiva or cornea by the cap is in and of its self not only irritating to the eye, but the irritation to the eye can delay or impair recovery of the eye from the primary disease being treated by the implant.

In the present invention and as claimed in claims 1 through 4, the implant structure prevents the thin elongated lip from engaging, contacting or otherwise abrading the surface of the eye including the cornea or conjunctiva. This is a material and important difference between the present invention and the prior art including Guena et al.

Independent claims 1-4 sharply and clearly define and claim a structure over the prior art and for consistency to define the lip as "a thin elongated lip". The reason for the use of the term "thin elongated lip" in the claims is that term is defined in the Specification, as amended, at Page 23, lines 13 through 21 which is as follows:

For purposes hereof, the term "thin elongated lip" means an extension or lip which extends or protrudes beyond the outer surface of the elongated member and which would be located around approximately 300° or less of the periphery of the elongated member leaving the posterior surface thereof free from

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protruding into, or from contacting with or abrading the surface of the eye including the cornea or conjunctiva [Underlining added for emphasis].

Thus, the thin elongated lip has the posterior surface therefor adjacent a surface of an eye including the cornea or conjunctiva free from an edge which would otherwise contact or abrade the surface of an eye. Clearly, this specific structure and solution to the prior art problems is not shown, disclosed, suggest or taught by Guena et al. This structure as claimed herein is new, novel and unique.

In addition and as shown in Fig. 4(b) of the present Application, for example, the lateral end 54 may be slightly angularly disposed relative to the medial end 36 to further insure that the posterior portion of the thin elongated lip 38 located near the cornea or conjunctiva does not contact or abrade the surface of the eye. This is in addition to the structure itself not having any posterior surface adjacent the surface of an eye. The combination of the absence of any posterior surface on the thin elongated lip adjacent the surface of an eye and a slight angular disposition of the shaft away from the surface of the eye as disclosed and claimed herein is also new, novel and unique.

Guena et al. tilting of the flange 3 is not the same as and does not disclose, suggest or teach moving or positioning the edge of the cap away from the surface of an eye including the cornea or conjunctiva. In fact, Guena et al. teaches just the opposite to wit: "The tilting of the flange allows [the flange] to have full contact between the cornea and the flange [column 2,

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lines 60 through 65]." which clearly results in the cap engaging, contacting and otherwise abrading the cornea.

For all of the above reasons, the Examiner's rejection Claims 1-4, as amended, under 35 U.S.C. § 102(b) as anticipated by Guena et al. United States Patent 5,417,651, has been overcome.

The Examiner rejected claims 1 through 3 and 18 under 35 U.S.C. § 102(b) as being anticipated by Seder et al United States Patent 4,959,048. In making this rejection, the Examiner stated as follows:

- a. With respect to claims 103, see Figure 4 for a punctum plug (100) comprising an elongated member (106) having a thin elongated lip (104) which is positioned in a generally anterior direction upon insertion in to a punctum opening, the thin elongated lip having a posterior edge which is positioned away from the cornea, wherein one end is curved anteriorly relative to the thin elongated tip.
- b. With respect to claim 5, see Figure 4 for a punctum plug (100 comprising an elongated member having at one end a lip (104), the elongated member having a portion curved anteriorly relative to the lip.
- c. With respect to claim 18, see Figure 4 wherein the other end of the punctum plug includes a shaped distal tip (108).

Applicant respectfully traverses this rejection for several important reasons.

Seder et al United States Patent 4,959,048 discloses a reversible, flexible, lacrimal duct occluder which is formed of a shaft having a low profile cap at one end and a rounded tip at

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the other end. The shaft has at least one, and preferably 1 through 3, conical ranges forward on the shaft between the ends. The rounded tip enters the punctum followed by the leading edge of the range(s) until the occluder bends at an acute angle relative to the axis of the shaft and enters the horizontal canalicular canal.

In practice, however, it has developed that the transition from that portion of the canaliculus adjacent the punctum opening, sometimes referred to as the vertical portion of this canaliculus, does not occur as a distinct transition point, but rather occurs through an intermediary section referred to as the ampula or sac which is anatomically an extension of that portion of the canaliculus that extends horizontally to the nasal sac.

Therefore, an implant which occludes the punctum opening and that portion of the canaliculus adjacent the punctum opening, depending on its length, can have a portion thereof located in the ampula or sac. By occluding the lacrimal drainage system in this manner, it is not necessary that the implant physically be located in that portion of the canaliculus which is beyond the ampula or sac to be effective.

On the other hand, if an implant, without a dome or collarette, is inserted into the punctum opening or the vertical section of the canaliculus, that implant generally migrates through the punctum opening through the portion of the canaliculus adjacent to the punctum opening, into the ampula or sac, and can easily migrate into that portion of the canaliculus beyond the ampula or sac.

Further, Fig. 4 of Seder et al is a lateral illustration and the elongated member simply extends in a plane parallel to the eye. As such the elongated member cannot and does not extend

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anterior to the surface of an eye to position the cap away from the surface of the eye. In fact, the lip 104 has exactly the same problem discussed above with respect to the disadvantages of the prior devices including Freeman and Guena et al., and that is the edge of the circular cap, dome or flange engages, contacts or otherwise abrades the surface of the eye including the cornea and conjunctiva.

As to Claim 18 of the present invention, the elongated member has a pair of ends wherein one of the pair of ends includes a shaped distal tip forming a starting tip having an outer surface. The other of the pair of ends includes a thin elongated lip having a posterior surface and the thin elongated lip is located on the elongated member to position the thin elongated lip in a generally anterior direction upon insertion in to a punctum opening to position the posterior surface away from a surface of an eye.

The structure of Seder et al does not disclose, teach or suggest the invention of Claim 18. The invention as claimed in Claim 18 includes a starting tip in addition to the thin elongated lip which extends in an anterior direction from the surface of the eye. This combination, likewise, is simply not disclosed, suggested or taught by Seder et al.

For all of the above reasons, the Examiner's rejection of Claims 1-3, 5 and 18, as amended, under 35 U.S.C. § 102(b) as anticipated by Seder et al United States Patent 4,959,048, has been overcome.

The Examiner rejected Claims 29 and 31-32 under 35 U.S.C. § 102(b) as being anticipated by Herrick United States Patent 5,163,959. In making this rejection, the Examiner stated as follows:

a. With respect to claim 29, see Figure 1 and 10(b) for a punctum plug comprising an elongated member having a central member (22) with predetermined cross-sectional dimension, the member having at one end a tip insertion section (26) having an offset (i.e., beveled or angled) distal starting tip (32), the offset distal starting tip having a smaller cross-section than the tip insert section, and wherein the member has a second end which comprises a thin elongated lip (34).

b. With respect to claims 31 and 32, see Figures 10(a) through 10(b) for the method of treating a tear deficiency with the recited punctum plug.

Applicant respectfully traverses this rejection for several important reasons.

In Herrick, United States Patent 5,163,959, the starting tip axis, as shown in Figs. 1 and 10(b), is concentric with the elongated axis and is in alignment with the tip insert section. As such, the tip insert section has an aligned starting tip. In the present invention, this is shown as Fig. 25 (f) which is labeled *PRIOR ART*.

In Figs. 26, 29, 30(a), 30(b), 30(c) 31 and 32, the starting tip axis is not concentric with the elongated axis, but is in fact offset from the tip insert section. As such, the tip insert section has an offset distal starting tip.

Claim 29 at lines 11 to 13 includes the following structural language:

wherein the tip insert section has an offset distal starting tip which is smaller in cross-sectional dimension than said tip

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insert section; [Underlining added for emphasis.]

Claim 31 at lines and 11 has similar structural language. Claim 32 is dependent on Claim 31, and is subject to this structure.

As such, it is very clear that Herrick United States Patent 5,163,959 does not disclose, suggest or teach a tip insert section having an offset distal starting tip nor that the offset tip has a smaller cross-sectional dimension than the tip insert section.

Applicant respectfully brings to the Examiner's attention that inventor Herrick of United States Patent 5,163,959 is the same inventor of the instant invention. Herrick conceived of the new concept of the offset distal starting tip to enhance insertion of a lacrimal plug into a punctum opening which is typically oval in shape. This concept is not disclosed in Herrick United States Patent 5,163,959 for the reasons set forth above.

For all of the above reasons, the Examiner's rejection of Claims 29 and 31-32 under 35 U.S.C. § 102(b) as being anticipated by Herrick United States Patent 5,163,959 has been overcome.

Double Patenting

Applicant acknowledges that the Examiner has rejected Claims 1 and 4 through 17 under the judicially created doctrine of double patenting over Herrick United States Patent 5,723,005.

In order to overcome this rejection, the undersigned,, as attorney of record, has signed and encloses herewith a TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A PRIOR

PATENT, namely, United States Patent 5,723,005, together with the Statutory Disclaimer Fee of \$55.00 required under 37 CFR 1.20(d).

With the filing of the Terminal Disclaimer and Payment of the Statutory Disclaimer Fee, the Examiner's rejection of Claims 1 and 4 through 17 over Herrick United States Patent 5,723,005 under the judicially created doctrine of double patenting has been overcome.

Allowable Subject Matter

Applicant acknowledges and appreciate the Examiner allowing Claims 20 through 28.

With respect to Claims 19 and 30, the Examiner stated that Claims 19 and 30 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office Action and to include all of the limitations of the base claim and any intervening claims.

Claim 19, which is dependent on Claim 18, has not been amended. Since Claim 18 is verily believed to be allowable, Claim 19 is being retained in the Application in its present condition on the basis that it varies the scope of the invention based on what is believed to be an allowable independent claim.

Claim 30 has been amended at line 4 by inserting the words "thin elongated" before the word "lip" such that the term now reads "thin elongated lip". In this manner, the rejections under 35 USC 112, first and second paragraphs, have been overcome.

Further, Claim 30 is dependent on Claim 29. Since Claim 29 is verily believed to be allowable, Claim 30 is being retained in the Application, as amended, on the basis that it varies the scope of the invention based on what is believed to be an allowable independent claim.

Of course, Applicant is not waiving its right, if it becomes necessary or desirable to do so, to rewrite the claims to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office Action and to include all of the limitations of the base claim and any intervening claims.

New Claims 32 through 37

Applicant has added new Claims 32 through 37 to this United States Patent Application and the additional claim fees therefore have been paid concurrently with the filing of this Amendment.

These claims are intended to more specifically claim the inventions including the embodiments illustrated in Figs. 27 and 28 and claimed variations thereof.

Claim 32 claims a punctum plug comprising an elongated central member having a central axis and a pair of ends wherein one of the pair of ends includes an enlarged annular shaped section terminating in a starting tip. An antecedent basis for this language appears at Page 45, lines 14 through 25 and Page 46, lines 1 through 13.

The starting tip is inserted into a punctual opening and urges the punctual opening into a dilated punctual opening capable of receiving and being further dilated by the enlarged annular shaped section in response to the application of force on the elongated central member in a direction to urge the enlarged annular shaped section through the dilated punctual opening. The elongated central member and the enlarged annular shaped section are formed of a dimension to pass through a punctual of an eye.

The sloped portion of the enlarged annular shaped section 248 is directed towards the distal starting tip as illustrated in Figs. 27 and 28. Independent of whether or not one side has a greater slop towards the starting tip, the sloped portion

performs the function of further dilating a punctual opening by urging the punctual opening into a dilated punctual opening capable of passing the enlarged annular shaped section in response to the application of force on the elongated central member in a direction to urge the enlarged annular shaped section through the dilated punctual opening.

The dependent claims 33 through 37 vary the scope of what is verily believed to be a patentable independent claim, it being noted that Claim 37 claims that structure of the embodiment of Fig 27 and 28 having one side having a greater slop towards the starting tip. As noted above, one side having a greater slop is not necessary, but enhances dilation of the punctual opening.

The invention covered by Claims 32 through 37 are verily believed to define a patentable invention over the prior art by virtue of the multi-step self-dilation effect of the enlarged annular shaped section in combination with an aligned starting tip.

Summary

Claim 1 through 31, as amended and as originally filed, and new Claims 32 through 37 are present in the Application.

The Examiner is respectfully requested to approve the correction to the Drawing.

With the filing of the Terminal Disclaimer concurrently with this Amendment, the double patenting rejection has been overcome. All of the claims presently pending in this United States Patent Application are verily believed to define patentable subject matter over the Cited Art.

For all of the above reasons, it is verily believed that this United States Patent Application is in condition for Allowance. The Examiner is respectfully requested to issue a Notice of Allowability and a formal Notice of Allowance.

Applicant will file the formal drawing, containing the correction approved by the Examiner, on or before payment of the Issue Fee.

If the Examiner determines that further amendments to the claims would render the same allowable or would facilitate the issue of a Notice of Allowance, the undersigned respectfully requests the Examiner to call the undersigned for an interview in order to expedite the issuance of a Notice of Allowance.

Respectfully submitted,



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